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Date: December 21, 2001 By: Jennifer Mahan

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Soos, J.M, *et al.*

SERIAL NO: Not yet Assigned

FILED: Concurrent Herewith

FOR: **ORALLY-ADMINISTERED INTERFERON-TAU COMPOSITIONS AND METHODS**

EXAMINER: Unknown

ART UNIT: Unknown

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to calculation of the filing fee and examination of the above-noted application, amend the claims as follows.

In the Claims: Cancel claims 6, 7, and 10-19 without prejudice; replace claims 1-5, and 9 with the following rewritten claims; and add new claims 20-36 as follows:

1. (Amended) In a method of treating a viral disease in a mammal responsive to treatment by ovine interferon-tau (IFN_τ), an improvement comprising orally administering a therapeutically-effective amount of bovine IFN_τ through oral ingestion.

2. (Amended) The method of claim 1, wherein IFN_τ is orally-administered at a dosage of greater than about $1x10^5$ units per day.

3. (Amended) The method of claim 1, wherein IFN_τ is orally-administered at a dosage of greater than about $1x10^6$ units per day.

4. (Amended) The method of claim 1, wherein the bovine IFN_τ has an amino acid sequence homology of at least about 80% with an ovine IFN_τ ($OvIFN_\tau$) amino acid sequence.

5. (Amended) The method of claim 1, wherein said bovine IFN_τ has a sequence homology of at least about 80% with an ovine IFN_τ sequence represented as SEQ ID NO:2.

9. (Amended) The method of claim 20, wherein said mammal is a dog.

20. (New) The method of claim 1, wherein the mammal is a domesticated animal.

21. (New) In a method of treating a condition associated with cellular proliferation in a mammal responsive to treatment by ovine interferon-tau (IFN_τ), an improvement comprising orally administering a therapeutically-effective amount of bovine IFN_τ through oral ingestion.

22. (New) The method of claim 21, wherein IFN_τ is orally-administered at a dosage of greater than about $1x10^5$ units per day.

23. (New) The method of claim 21, wherein IFN_τ is orally-administered at a dosage of greater than about $1x10^6$ units per day.

24. (New) The method of claim 21, wherein the bovine IFN_τ has an amino acid sequence homology of at least about 80% with an

ovine IFN_τ ($OvIFN_\tau$) amino acid sequence.

25. (New) The method of claim 21, wherein said bovine IFN_τ has a sequence homology of at least about 80% with an ovine IFN_τ sequence represented as SEQ ID NO:2.

26. (New) The method of claim 21, wherein said mammal is a human.

27. (New) The method of claim 21, wherein the mammal is a domesticated animal.

28. (New) The method of claim 27, wherein said mammal is a dog.

29. (New) In a method of treating an inflammatory disease condition in a mammal responsive to treatment by ovine interferon-tau (IFN_τ), an improvement comprising orally administering a therapeutically-effective amount of bovine IFN_τ through oral ingestion.

30. (New) The method of claim 29, wherein IFN_τ is orally-administered at a dosage of greater than about $1x10^5$ units per day.

31. (New) The method of claim 29, wherein IFN_τ is orally-administered at a dosage of greater than about $1x10^6$ units per day.

32. (New) The method of claim 29, wherein the bovine IFN_τ has an amino acid sequence homology of at least about 80% with an ovine IFN_τ ($OvIFN_\tau$) amino acid sequence.

33. (New) The method of claim 29, wherein said bovine IFN_τ has a sequence homology of at least about 80% with an ovine IFN_τ sequence represented as SEQ ID NO:2.

34. (New) The method of claim 29, wherein said mammal is a human.

35. (New) The method of claim 29, wherein the mammal is a domesticated animal.

36. (New) The method of claim 35, wherein said mammal is a dog.

REMARKS

Entry of the claim amendments and additions prior to examination is respectfully requested. Attached hereto is a marked up version of the changes made to the claims. The attached page is entitled **"Version with Markings to Show Changes Made."**

I. Amendments

Claim 1 has been amended to describe a method for treating a viral disease in a mammal. Basis for this amendment can be found, for example, on page 9, lines 20-24 and page 28, lines 5-31. Claim 1 is also amended to state that the IFN_τ is administered through oral ingestion, as described, for example on page 7, line 35 to page 8, line 1. Claim 1 further describes that the IFN_τ is bovine IFN_τ, as set forth on page 12, line 31.

Claims 2 and 3 are amended to describe that the IFN_τ is administered at a dosage of greater than about $1x10^5$ (claim 2) and about $1x10^6$ (claim 3) units per day. Basis for these amendments can be found on page 31, line 35 to page 32, line 11.

Claims 4 and 5 are amended to recite that the bovine IFN_τ has an amino acid sequence homology of at least about 80% with ovine IFN_τ amino acid sequence. Basis for this amendment can be found on page 12, line 31 to page 13, line 4.

Claim 9 is amended to depend from new claim 20, which describes an embodiment where the mammal treated with the IFN_τ is a domesticated animal. Basis for new claim 20 is on page 29, lines 25-27..

New claim 21 parallels claim 1 for treating a condition associated with cellular proliferation. Basis for treatment of this condition is found, for example, on page 28, line 34 to page 29, line 5 and on page 24, line 35.

Dependent claims 22-28 parallel dependent claims 2-5, 8, 9 and 20, discussed above.

New claim 29 parallels claim 1 for treating an inflammatory disease condition in a mammal, as described, for example, on page 24, line 34.

Dependent claims 30-36 parallel dependent claims 22-28 and 2-5, 8, 9, and 20.

Accordingly, no new matter is added by these amendments.

Respectfully submitted,

Date: 12/21/01

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) In a method of treating a viral disease [condition] in a mammal responsive to treatment by ovine interferon-tau (IFN_τ), an improvement comprising orally administering a therapeutically-effective amount of bovine IFN_τ through oral ingestion.

2. (Amended) The method of claim 1, wherein IFN_τ is orally-administered at a dosage of [between] greater than about $1x10^5$ [and about $1x10^8$] units per day.

3. (Amended) The method of claim [2] 1, wherein IFN_τ is orally-administered at a dosage of [between] greater than about $1x10^6$ [and about $1x10^7$] units per day.

4. (Amended) The method of claim 1, wherein the bovine IFN_τ has an amino acid sequence homology of at least about 80% with an [orally-administered IFN_τ is] ovine IFN_τ ($OvIFN_\tau$) amino acid sequence.

5. (Amended) The method of claim 1, wherein said [$OvIFN_\tau$] bovine IFN_τ has [the] a sequence homology of at least about 80% with an ovine IFN_τ sequence represented as SEQ ID NO:2.

9. (Amended) The method of claim [1] 20, wherein said mammal is a dog.